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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,370	05/03/2005	Karl Stangl	2958-130	1382

6449 7590 01/25/2007  
ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
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SUITE 800  
WASHINGTON, DC 20005

EXAMINER
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NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	01/25/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 01/25/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,370	<b>Applicant(s)</b> STANGL ET AL.	
	<b>Examiner</b> Ronald T. Niebauer	<b>Art Unit</b> 1609	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a special technical feature is to make a contribution over the prior art. Claim 1 is drawn to a use of at least one proteasome inhibitor for the treatment of fibrotic diseases, which are not caused by inflammatory responses to foreign matters. Gyorkos et al US 6255453 teaches the use of protease inhibitors for the treatment of conditions including cystic fibrosis (see abstract of US 6255453). Therefore the claimed invention makes no contribution over the prior art, consequently there is no special feature uniting the claimed invention.

The species are as follows:

Disease type: cardiac, liver, kidney, or joint fibrosis (as recited in claim 2); lung, liver, skin, joints, skeleton, glands or fibrotic disease (as recited in claim 6)

Fibrosis cause: (only if cardiac fibrosis is elected) overload under chronic pressure stress in arterial hypertension or overload in compensatory hyperkinesias of the intact residual myocardium in case of myocardial infarction (as recited in claim 3)

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Treatment agent: (only if cardiac fibrosis is elected) ACE inhibitors, AT-1

antagonists, or endothelin antagonists (as recited in claim 4)

Proteasome inhibitor: low-molecular organic compound, molecular-biological compound (as recited in claim 7)

Proteasome inhibitor: threonine protease inhibitor, a serine protease inhibitor, a cysteine protease inhibitor, a gene expression inhibitor of the proteasomal system, or a binding protein or binding peptide (as recited in claim 8)

Proteasome inhibitor:

(Note: since claim 9 and 10 both refer to proteasome inhibitors applicant should elect a structure of claim 9 and an embodiment thereof from claim 10.)

a peptide aldehyde, a peptide boronate, a peptide vinyl sulfone, a peptide epoxyketone, a lactacystine, a peptide alpha keto-aldehyde, an alpha-ketoamide, an indanone peptide, a polyalkylene aldehyde, a polyphenol, in particular a catechin-3-gallate, a nucleic acid (as recited in claim 9).

Proteasome inhibitor: Z-Leu-Leu-Leu-al (MG132), Z-Ile-Glu(OtBu)-Ala-Leu-al (PSI), CEP1612, pyrazylcarbonyl-Phe-Leu-boronate (PS-341), dansyl-Phe-Leu-boronate (DFLB), morpholino-naphthylalanine-Leu-boronate (MG273), NIP-Leu3-vinylsulfone (NLVS), Tyr-Leu3-VS, NIP-Leu-Leu-Asn-VS, Ada-Tyr-Ahx3-Leu3-VS, Ada-Lys(Bio)-Ahx3-Leu3-VS, Ac(Me)-Ile-Ile-Thr-Leu-EX (epoxomicin), dihydroeponemycin, lactacystine, clasto-lactacystine-beta-lactone (omuralide), PS-519, Ac-Leu-Leu-Nle-al (ALLN), 3,4-dichloroisocoumarine (DCI), 4-(2-aminoethyl)-benzenesulfonyl fluoride (Pefablock SC), TMC-95A, gliotoxin, (-)-

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epigallocatechin-3-gallate (EGCG), ritonavir, lovastatin, aclacinomicin A (Aclarubicin), cyclosporin, an anti-sense-RNA or a double-stranded RNA (dsRNA) against a proteasome encoding sequence, a triplex forming oligonucleotide against a proteasome encoding sequence and/or a knock-out construct against a proteasome encoding sequence, wherein Z is a benzyloxycarbonyl group, al is an aldehyde group, VS is a vinyl sulfone group, NIP is a 3-nitro-4-hydroxy-5-iodophenylacetate group, and Bio is a biotin group (as recited in claim 10).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

See above – claim number is noted after each species

The following claim is generic: 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Gyorkos et al US 6255453 teaches the use of protease inhibitors for the treatment of conditions including cystic fibrosis (see abstract of US 6255453). Therefore the claimed invention makes no contribution over the prior art, consequently there is no special feature uniting the claimed inventions.

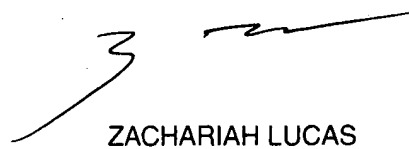
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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-272-0235. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ZACHARIAH LUCAS  
PATENT EXAMINER